

FEB 20 2007

Atty Dkt. No.: STHP-018
USSN: 10/507,931**REMARKS**

In view of the following remarks, the Examiner is requested to allow Claims 1-21, the only claims pending and under examination in this application.

As an initial matter, the Applicants request that the finality of this rejection be withdrawn. In the Office Action that issued on May 12, 2006, The Office inadvertently withdrew Claims 4-21 from consideration. Consequently, Claims 16-21 were not considered on their merits. Hence, the present 35 U.S.C. §§ 102(b) and 103(a) rejections of Claims 16-21 constitute new grounds of rejection that were not necessitated by the Applicants' amendments. Accordingly, the Applicants contend that the finality of this Office Action is premature and the Applicants respectfully request it be withdrawn.

Claim Rejections – 35 U.S.C. § 102

Claims 1-6, 9-11 and 19-21 have previously been rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Nishimura (USPN 5,137,028).

An element of the rejected claims is an indwelling vaginal thermometer. As defined by the Merriam-Webster Online Dictionary, the term indwelling means: left within a bodily organ or passage to maintain drainage, prevent obstruction, or provide a route for administration of food or drugs. As an example of the term "indwelling," the Merriam-Webster dictionary cites a catheter.

As is readily understood by one of skill in the art, there are two basic types of catheter, those that are "in-out" and those that are "indwelling." Specifically, an "in-out" catheter is one that is applied to the body for a given procedure and then removed. An "in-out" catheter is typically used in out patient settings and is applied over the matter of minutes. An "indwelling catheter," on the other hand, is not one that is applied and then

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removed over a period of minutes, but rather an "indwelling catheter" is a catheter that is placed within a passage of the body and left there for a long period of time, such as weeks or months (e.g., so as to promote drainage). See, for instance, Exhibit A.

An indwelling thermometer is similar to an indwelling catheter in that, as is widely known in veterinary practices and animal husbandry, an "indwelling thermometer" is one that is placed within the body for a long period of time. Hence, an "indwelling" thermometer is not an "in-out" thermometer. This understanding is in accordance with the way the term "indwelling thermometer" is used in the Applicant's specification. According to the Applicant's specification, an indwelling thermometer is a thermometer which is left in a predetermined place for a long period of time. See paragraph 5.

The Office asserts that Nishimura discloses an "indwelling" thermometer that is inserted into a body for a period of minutes (e.g., five minutes). The Office asserts that because minutes are a long period of time when compared to seconds, Nishimura discloses an indwelling thermometer as recited in the Applicants' Claim 1.

The rejection of the Office, however, is premised upon the assumption that the Nishimura device is capable of performing the same function as that of the Applicants' thermometer. The Office asserts that "if the prior art structure is capable of performing the intended use [as the Applicants' device], then it meets the claim [limitations]."

The Applicants respectfully disagree. The Applicants' contend that the Nishimura device is an "in-out" thermometer that is not capable of performing as an "indwelling" thermometer, nor would one of skill in the art consider the Nishimura device an "indwelling" thermometer.

The Applicant's specification defines "indwelling" as one that is left in a predetermined place for a long period of time. Nowhere does Nishimura teach that the disclosed thermometer is left within the body for a long period of time. In fact, the

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Applicants contend that the thermometer disclosed in Nishimura would not be capable of functioning properly if it were to "indwell" within a body for a prolonged time period.

The thermometer disclosed in Nishimura functions to accurately determine the day of ovulation. In order to accurately determine the day of ovulation, a user must frequently enter and update data into the device, such as bleeding, menorrhagia, discharge, intercourse, fever, doping and the like. See column 4, lines 22 to 49. Such data input requires that the user continuously push buttons on the device in order to input information and to record temperatures. In fact, as indicated by column 6, lines 10 to 17, two buttons need to be depressed in order to take a single measurement. The Office has not described just how one is supposed to depress one, let alone two, buttons on the Nishimura thermometer while it is indwelling within a vagina.

On the contrary, the Applicants contend that the configuration of the Nishimura thermometer makes it physically impossible to use the device as a vaginally indwelling thermometer. Hence, contrary to the assertion of the Office, the thermometer of Nishimura is not capable of performing the same function as that of the Applicants' thermometer and, therefore, would not be considered an "indwelling" thermometer by one of skill in the veterinary or medical arts.

Further, the Office asserts that the insertion of a portion of a thermometer into a body for a period of minutes, as disclosed by Nishimura, makes the disclosed thermometer an "indwelling" thermometer, because a period of "minutes" constitutes a "long period of time." The Applicants respectfully disagree.

As described above, a person of skill in the art would recognize the difference between an "indwelling" thermometer, as recited in the Applicants' claims, and an "in-out" thermometer, as disclosed in Nishimura. For instance, the thermometer disclosed by Nishimura functions to indicate the time at which point the body temperature of a person being supervised is to be measured. Hence, when viewed in its entirety, the

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disclosure of Nishimura indicates that the thermometer is only used to take measurements at predetermined, periodic times and for short time durations. Accordingly, the Nishimura thermometer is designed to be inserted, a measurement taken, and then removed after the measurement is taken. The duration of time during which a measurement is taken is short, for instance, up to 5 minutes.

In contrast, in certain embodiments, the Applicants' indwelling thermometer is placed within a vagina for at least a complete menstrual cycle. See paragraph 83. Hence, when viewed in light of the Applicants' teachings of placing an indwelling thermometer within a vagina, for instance, over night and even up to 28 days, one of skill in the art would not consider the 5 minute measurement period disclosed in Nishimura to be a "long period of time."

Therefore, as the thermometer disclosed in Nishimura does not *indwell* in a predetermined place (e.g., a vagina) for a long period of time (e.g., an entire menstrual cycle), one of skill in the art would not consider the Nishimura thermometer to be indwelling. Rather, because the Nishimura thermometer is only inserted and removed over a period of five minutes, one of skill in the art would consider the Nishimura thermometer to be an "in-out" thermometer. Hence, because the disclosed Nishimura thermometer is not a vaginally indwelling thermometer, Nishimura fails to teach every element of the Applicant's claims. Consequently, the Applicant contends that Nishimura does not anticipate the claimed invention and respectfully requests that the 35 U.S.C. § 102(b) rejection of Claims 1-6, 9-11 and be withdrawn.

Claim Rejections – 35 U.S.C. § 103

Claims 7-8 have been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Nishimura in view of Nollen (USPN 3,895,523).

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According to the MPEP § 706.02 (j), to establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.

Claims 7 and 8 ultimately depend from Claim 1. As set forth above, an element of the rejected claims is an indwelling vaginal thermometer.

The Office acknowledges that Nishimura does not teach a temperature sensing means that includes a wax or a grease with a melting point close to a temperature threshold. The Office, therefore, relies upon Nollen for its teaching of a disposable thermometer that includes a dye and Vaseline. However, as set forth above, Nishimura is deficient for failing to teach an indwelling vaginal thermometer. As Nollen was cited for its teaching of a disposable thermometer that includes a dye and Vaseline, it fails to remedy the teachings of Nishimura. Therefore, a *prima facie* case of obviousness has not been established because the cited combination fails to teach every element of the rejected claims, namely, an indwelling vaginal thermometer. Accordingly, in view of this, the Applicant respectfully requests that the 35 U.S.C. § 103(a) rejection of Claims 7 and 8 be withdrawn.

Claims 12-13 have been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Nishimura in view of Hof *et al.* (USPN 4,345,470).

Amended Claims 12 and 13 ultimately depend from Claim 1. As set forth above, an element of the rejected claims is an indwelling vaginal thermometer.

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The Office acknowledges that Nishimura does not teach the material from which the thermometer is made or thermochromatic temperature sensing means. The Office, therefore, relies upon Hof for its teaching of a thermometer that is made from plastic and includes an indicator means that is heat sensitive and changes color in response to a temperature change.

However, as set forth above, Nishimura is deficient for failing to teach an indwelling vaginal thermometer. As Hof was cited for its teaching of an indicator means that is heat sensitive and changes color in response to a temperature change, it fails to remedy the teachings of Nishimura. Therefore, a *prima facie* case of obviousness has not been established because the cited combination fails to teach every element of the rejected claims, namely, an indwelling vaginal thermometer. Accordingly, in view of this, the Applicant respectfully requests that the 35 U.S.C. § 103(a) rejection of Claims 12 and 13 be withdrawn.

Claims 14-21 have been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Nishimura in view of Weiland (USPN 5,499,631).

Claims 14-18 are directed to a kit of thermometers. The kit includes a series of thermometers, wherein each thermometer detects a different predetermined threshold temperature across a range of temperatures.

The Office acknowledges that Nishimura only discloses a single temperature sensing means. The Office, therefore, relies upon Weiland to remedy the deficiencies of Nishimura. Weiland, however, does not teach a kit of thermometers that includes a plurality of thermometers wherein each thermometer detects a different predetermined threshold temperature across a range of temperatures. Rather, Weiland teaches a test probe that includes multiple test electrodes which are attached to the test probe. The primary function of the test electrodes is to measure electrical conductivity. Hence, the different test electrodes disclosed in Weiland do not detect different predetermined

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threshold temperatures across a range of temperatures as recited in the Applicants' claims. Accordingly, as neither Nishimura nor Weiland teach a plurality of thermometers wherein each thermometer detects a different predetermined threshold temperature across a range of temperatures, the recited combination fails to teach every element of the rejected claims.

With respect to Claims 19 – 21, the Office has not set forth where the elements of the rejected claims are taught or suggested by the recited combination. Further, Claims 19 – 21 ultimately depend from Claim 1. As set forth above, Nishimura is deficient in that it fails to teach every element of rejected Claim 1. As Weiland was cited solely for its teaching of a kit of multiple sensing means it fails to remedy the deficiencies of Nishimura.

Therefore, a *prima facie* case of obviousness has not been established. Accordingly, in view of this, the Applicant respectfully requests that the 35 U.S.C. § 103(a) rejection of Claims 14 – 21 be withdrawn.

Claim 15 has been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Nishimura in view of Weiland and further in view of Nollen.

Claim 15 depends from Claim 14. An element of Claim 14 is a kit that includes a series of thermometers, wherein each thermometer detects a different predetermined threshold temperature across a range of temperatures. As described above, the combination of Nishimura and Weiland is deficient in that it fails to teach every element of the rejected claims, namely, a kit that includes a series of thermometers, wherein each thermometer detects a different predetermined threshold temperature across a range of temperatures. Nollen as well does not teach this element. Accordingly, the cited combination fails to teach every element of the rejected claims. Therefore, a *prima facie* case of obviousness has not been established. Accordingly, in view of this,

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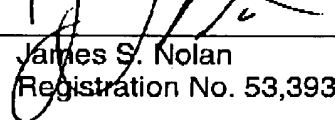
the Applicant respectfully requests that the 35 U.S.C. § 103(a) rejection of Claim 15 be withdrawn.

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Applicant submits that all of the claims are in condition for allowance, which action is requested. If the Examiner finds that a telephone conference would expedite the prosecution of this application, please telephone Bret Field at (650) 833-7770.

The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-0815, order number STHP-018.

Respectfully submitted,
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Date: 2-20-07By: 
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Enc: Exhibit A.

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